

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Michael Wandell et al.	Examiner:	Lore Ramillano
Application No.:	10/706,321	Art Unit:	1797
Filing Date:	November 12, 2003	Docket No.:	36664.00.0013
Confirmation No.:	6492		

Title: **QUANTITATIVE ANALYSIS OF A BIOLOGICAL SAMPLE OF
UNKNOWN QUANTITY**

Mail Stop AF
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF

Dear Sir:

Pre-Appeal is respectfully requested. Applicant files this Pre-Appeal Brief along with a Notice of Appeal. Pre-appeal review is the proper recourse when a rejection is based either on a clear error in law or when the Examiner fails to set forth a *prima facie* case against patentability, omitting one or more elements or limitations required in a claim. See *OG Notice*, July 12, 2005, New Pre-Appeal Brief Conference Pilot Program. In this case, the Examiner argues as part of the *prima facie* case that by drawing a small circle using a pen on a flat, continuous sheet of paper, an "aperture" having a "blood receiving opening" is created in the paper.

As a reminder, all remaining claims (claims 4–15, 20–21, and 42) stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Quattrocchi (U.S. Patent No. 6,014,438) in view of Fitzgerald et al. (U.S. Patent No. 6,528,321). Claims 4, 6, and 42 are independent and include the aperture and opening discussed hereafter as part of claim 4. Applicant has made several arguments during prosecution, and these substantive arguments are reserved for the appeal process. The Examiner's confusion as to how drawn marks can be apertures is particularly adapted to the pre-appeal process as being an abuse of discretion. Claim 4 provides the following:

4. A fluid collection device comprising a fluid collector with an absorbent substrate coated with a saccharide, said substrate comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking and a superstrate, said fluid collector being generally fixed with respect to said superstrate, said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector.

Applicant's Fig. 9 reproduced below illustrates the fluid collection device 900 where two fluid collectors 903 and 904 are disposed over a fixed superstrate 905. Two apertures 909 and 910 allow users to prick their fingers and place the bleeding finger on the fluid collector directly through what is called blood-receiving openings. The shaded portion between the large arrows is tainted with blood from the finger, and as the blood migrates up the fluid collectors, a user will see a portion of the fluid collector through the secondary apertures turn red 911, 912 with blood. On this device, small strips are used and stabilized using the superstrate.

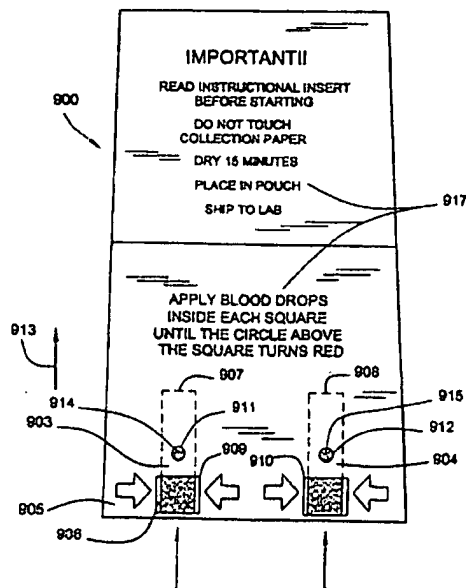
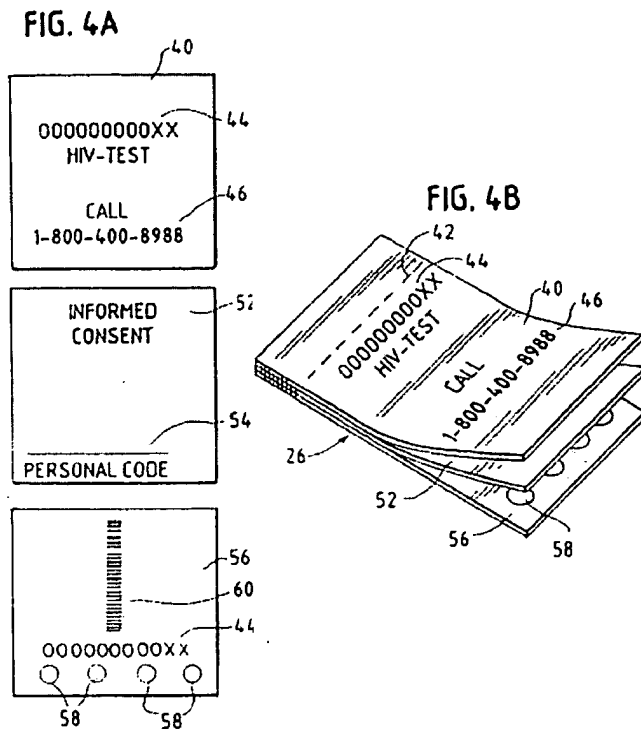


Fig. 9 of Application No. 10/706,321

In the *prima facie* case, the Examiner cites U.S. Patent No. 6,014,438 (Quattrocchi). Quattrocchi is a decade-old technology owned by Applicant. Figures 4A and 4B of the fluid collection device of that reference are shown below.



This older technology is simpler and has obvious disadvantages. Subsequent to a request for reconsideration, Applicant brought the following portion of the Quattrocchi specification to the attention of the Examiner in a phone conversation:

FIGS. 4A and 4B schematically illustrate one form of blood specimen collection card 26 which is preferably configured in a diagnostic form having three (3) parts. The first part is a removable top sheet 40. Perforations 42 are preferably provided to enable the person being tested to remove the top sheet 40 from the remainder of the collection card 26. Printed on the top sheet 40 is information that the person being tested needs to retrain after the remainder of the collection card 26 is sent for analysis. Col. 6, ll. 54-63.

The second part of collection card 26 is an informed consent form 52. The informed consent form 52 contains a series of statements that the person being tested must read, understand, and acknowledge before a laboratory can perform any test on the specimen. Col. 7, ll. 23-26.

In its illustrated form, the third part of collection card 26 is a blood specimen sample sheet 56. Sample sheet 56 is at least in part a cotton fiber filter paper preferably like that manufactured by Schleicher and Schuell. Sample sheet 56 has a blood collection area specifically designed thereon. In the illustrated embodiment, four similarly shaped sections 58 are outlined thereon for deposit of a specimen in each section. The sections 58 are outlined using black biological ink so that the ink will not interfere with the specimen and an accurate test result can be obtained. Col. 7, ll. 32-42 (emphasis added).

The old technology requires the entire sheet to be made of expensive blood-retaining media. Ink circles are drawn on a flat piece of paper, and users were required to place the finger in the circle and try to get the blood to diffuse over the entire area of the circle. There is no built-in protection for the blood sample, and it would then be mailed and rub directly against other bodies during transportation. Once at the laboratory, a circular punch system was used to remove the surface area inside the ink circles to collect the part of the substrate to dilute for measurement. If part of the circle was still white, the measure would be skewed.

The Examiner's position is best summarized by the continuation comment to the Advisory Action of September 11, 2008: "the Office takes the position that specimen sections (58) may be broadly interpreted to be openings. Furthermore, it appears that Quattrocchi's apertures read on applicant's apertures since applicant's apertures, like Quattrocchi, are filled with the fluid collector material, which includes an absorbent substrate."

During patent examination, pending claims must be given their broadest reasonable interpretation consistent with the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). Words of a claim must be given their plain meaning unless this meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989). The *Merriam-Webster's Collegiate Dictionary*, 10th ed. defines "aperture" as an opening or open space: hole. In turn, "opening" is defined as something that is open. (See Exhibit A attached hereto).

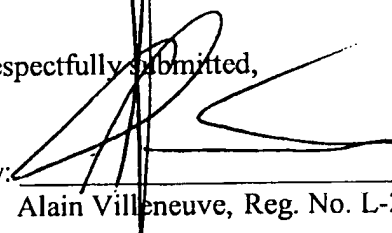
In *Mechanics of Patent Claim Drafting*, 2nd. ed., Landis explains, "Do not claim holes positively or make them claim elements. Holes are nothing; you cannot claim nothing. Claim "[member] having a hole, groove, slot, aperture, etc." Section 23. A copy of the relevant pages from this reference is attached as Exhibit B. Applicant respected this suggested format to claim the hole as an aperture of the superstrate and wrote, "... said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector." The claim language is perfectly clear.

The Examiner confuses a structure having a fluid collector, a substrate, and a superstrate, with the aperture on the superstrate. Quattrocchi is a structure with a fluid collector and a superstrate and no apertures on either the fluid collector or the substrate.

Rules are given to the Examiner if she wants to constitute a valid *prima facie* case where ink circles constitute apertures. She must either prove that Applicant's specification supports this particular meaning—that the plain meaning of these words support this interpretation—or that one of ordinary skill in the art agrees with the Examiner. MPEP § 2111. The position taken by the Examiner is contrary to almost every patent claim recorded with this Office. Apertures and openings in a media are precisely that: an aperture or an opening. Applicant asks this Board under what possible circumstance can writing or printing the number 8 on a piece of paper result in an apparatus with two apertures or two openings?

The use of the term "aperture" and "opening" is well established under modern patent practice. Apertures and openings are normal terminology used to claim holes. The plain meaning of these words is well known and unambiguous. Quattrocchi is a device with a fluid collector without neither an aperture nor an opening. The Examiner's position is contrary to common sense and patent law. The Examiner cannot argue that Applicant's apertures should be broadly construed to include surface areas within ink circles. Accordingly, Applicant requests reconsideration and withdrawal of the rejection and issuance of a Notice of Allowance for all claims.

Respectfully submitted,

By: 
Alain Villeneuve, Reg. No. L-215

Date: September 23, 2008

Vedder Price P.C.
222 N. LaSalle St., Suite 2600
Chicago, Illinois 60601
phone: (312) 609-7745
fax: (312) 609-5005



Merriam- Webster's Collegiate[®] Dictionary

TENTH EDITION

Merriam-Webster, Incorporated
Springfield, Massachusetts, U.S.A.

open-er \ˈoʊ-pən-, ˈoʊ-pə-\ *n* (15c): one that opens (a bottle ~); as pl: cards of sufficient value for a player to open the betting in a poker game **b**: the first item, contest, or event of a series — **for open-er**: to begin with
open-eyed \ˌoʊ-pan-ɪd/ *adj* (1601) **1**: having the eyes open **2**: candidly observant : DISCERNING
open-handed \-han-dəd/ *adj* (1593) : GENEROUS, MUNIFICENT — **open-handed-ly** *adv* — **open-hand-ed-ness** *n*
open-heart *adj* (1960) **1**: of, relating to, or performed on a heart temporarily relieved of circulatory function and surgically opened for inspection and treatment (~ surgery)
open-heart-ed \ˌoʊ-pan-ˈhɑr-təd/ *adj* (1611) **1**: candidly straightforward : FRANK **2**: responsive to emotional appeal — **open-heart-ed-ly** *adv* — **open-heart-ed-ness** *n*
open-hearth *adj* (1885) **1**: of, relating to, involving, or produced in the open-hearth process (**1882**) : a process of making steel from pig iron in a furnace with the regenerative reverberatory type
open-house *n* (15c) **1**: ready and usu. informal hospitality or entertainment for all comers **2**: a house or apartment open for inspection esp. by prospective buyers or tenants
opening \ˈoʊ-nɪŋ, ˈoʊ-pə-\ *n* (13c) **1a**: an act or instance of making or becoming open **b**: an act or instance of beginning : COMMENCEMENT; esp.: a formal and usu. public event by which something new is put officially into operation **2**: something that is open: as (1) : BREACH, APERTURE (2) : an open width : SPAN **b**: an area without trees or with scattered usu. mature trees that occurs as a break in a forest **c**: two pages that face one another in a book **3**: something that constitutes a beginning: as **a**: a planned series of moves made at the beginning of a game of chess or checkers — compare BENDGAME, MIN-DLE GAME **b**: a first performance **4a**: OCCASION, CHANCE **b**: an opportunity for employment
open letter *n* (1878) : a published letter of protest or appeal usu. addressed to an individual but intended for the general public
open loop *n* (1947) : a control system for an operation or process in which there is no self-correcting action as there is in a closed loop
open marriage *n* (1971) : a marriage in which the partners agree to let each other have sexual partners outside the marriage
open-minded \ˌoʊ-pan-ˈmɪnd-dəd/ *adj* (1828) : receptive to arguments or ideas — **open-minded-ly** *adv* — **open-minded-ness** *n*
open-mouthed \ˌoʊ-pan-ˈmaʊθ-d/, -ˈmaʊθl̩-/ *adj* (15c) **1**: CLAMOROUS VOCIFEROUS **2**: having the mouth wide open **3**: struck with amazement or wonder — **open-mouth-ed-ly** *adv* — **mai-thud-lē**, -thəd-*adv* — **open-mouth-ed-ness** \-maʊ-thəd-nəs, -thəd-*n*
open-poll-il-na-ted \ˌoʊ-pan-ˈpɔl-ɪ-l̩-, nā-təd/ *adj* (1925) : pollinated by natural agencies without human intervention
open season *n* (ca. 1890) **1**: a period when it is legal to kill or catch game or fish protected at other times by law **2**: a time during which someone or something is the object of sustained attack or criticism
open secret *n* (1828) : a supposed secret but generally known matter
open sentence *n* (1937) : a statement (as in mathematics) that contains at least one blank space or unknown and that becomes true or false when the blank is filled or a quantity is substituted for the unknown
open ses-a-me \-sə-sə-mē/\ *n* [fr. *open sesame*, the magical command used by Ali Baba to open the door of the robbers' den in *Ali Baba and the Forty Thieves*] (ca. 1837) : something that unawfully brings about a desired end
open shop *n* (1903) : an establishment in which eligibility for employment and retention on the payroll are not determined by membership or nonmembership in a labor union though there may be an agreement by which a union is recognized as sole bargaining agent
open sight *n* (1591) : a firearm rear sight having an open notch
open stance *n* (1948) : a stance (as in golf) in which the forward foot is farther from the line of play than the back foot — compare CLOSED STANCE
open syllable *n* (1891) : a syllable ended by a vowel or diphthong
open up vt (1582) **1**: to make available **2**: to make plain or visible : DISCLOSE **3**: to begin by cutting into ~ *vi* **1**: to spread out or come into view (the road **opens up ahead**) **2**: to commence firing **3**: to become communicative (try to get the patient to **open up**)
open-work \ˌoʊ-pən-ˈwɜrk-/ *n*, often attrib (1598) : work constructed so as to show openings through its substance : work that is perforated or pierced (wrought-iron ~) — **open-worked** \-wɜrk-t̩-/ *adj*
opera pl OF OPUS
op-er-a \ˌoʊ-pə-(r)-ə/, Southern also ˈä-prē/\ [It., work, opera, fr. L. work; pains; akin to L. oper-, opus — more at OPERATE] (1644) **1**: a drama set to music and made up of vocal pieces with orchestral accompaniment and orchestral overtures and interludes; specif.: GRAND OPERA **2**: the score of a musical drama **3**: the performance of an operatic piece : a house where operas are performed
op-er-a-ble \ˈä-pə-(r)-ə-bl̩-/ *adj* (1646) **1**: fit, possible, or desirable to use : PRACTICABLE **2**: likely to result in a favorable outcome (operable surgical treatment) (an ~ cancer) — **op-er-a-ble-ly** *adv* — **op-er-a-ble-ness** *n*
op-er-a-bon-fide \ˈä-pə-(r)-ə-bl̩-/ *adv* (1770) : bona fide
op-er-a-bon-fide \ˈä-pə-(r)-ə-bl̩-/ [F, fr. It. opera buffa] (1770) : satirical comic opera
op-er-a-buff \ˈä-pə-(r)-ə-bl̩-/ [lit., lit., comic opera] (1802) : an 18th-century farical comic opera with dialogue in recitative
op-er-a-comique \-kä-ˈmɛk-, -kō-/ [F, lit., comic opera] (1744) : an opera characterized by spoken dialogue interspersed between the acts and ensemble numbers — compare GRAND OPERA
op-er-a-glass *n* (1738) : a small low-power binocular without prism lens use at the opera or theater — often used in pl.
op-er-a-go-er \ˈä-pə-(r)-ə-gō-ər-/ *n* (1850) : a person who frequently goes to operas — **op-er-a-go-ing** \-gō-ɪŋ-, -gō-ɪŋ-/ *adj*
op-er-a-hat *n* (1810) : a man's collapsible top hat
op-er-a-house *n* (1720) : a theater devoted principally to the performance of operas; broadly : THEATER
op-er-and \ˈä-pə-(r)-ənd-/ *n* [L. *operandum*, neu. of gerundive of operari (1886) : something (as a quantity or data) that is operated on (as in a mathematical operation); also : the address in a computer instruction used to be operated on
op-er-at- \ˈoʊ-pə-rət-/ *adj* (15c) **1**: functioning or tending to produce effects REPERCUSSIVE (an ~ conscience) **2**: of or relating to the production of effects REPERCUSSIVE (an ~ conscience) **2**: of or relating to the production of effects REPERCUSSIVE (an ~ conscience)

arrivable or meas
and conditioning
n (1937,
that operates on
ing effects
operational condi
terior or increas
standing or reinfo
oper-se-ria V-sei
century opera w
operate V-a-p
operate to work
oper-wor V (15
ence (factors) op
erate effect (The
tion of a series of
ing or naval
is often irreg
: REINO ABOUT, I
we keep in operat
surgery on
oper-ic-lô V-a-p
grand, dramatic
-ô-jei adv
operating adv (18
expenses) (a hos
operating system
computer and dir
the space in mem
oper-ation V-a-p
operating, to op-
eration, or of some
processes 2 a
b: the quality or
in ~ c: a
simple ~ 3: E
4: a procedure c
for the repair of d
mathematical or l
from others accor
nevertheless includi
flight line of an ai
ligned with cari
with the headquar
ation esp. when a
in the execution
oper-ation-âl V-si
operation or to an o
tion 2: of, relat
g connected with
sion or battle b
section ~ oper-
ation-âl-issz
in concepts or ter
feasible in terms
oper-ation-âl V-si
-âl V-si -âl V-si
-âl V-si -âl V-si
oper-ation-issz V
oper-ation-issz V
operations retri-
mathematical met
complex systems
oper-ative V-a-p
propative effect: t
ating 3 a: havin
WORKING (an ~
the (~ density)
operative n (ca. 1
operant agent c: P)
oper-ator V-a-p
-ator that operates
c: one that
stocks person who
3 a: a somewhat
mathematical
lating site in a DP
is the initiation of
superstructural g
oper-ator-for-less
oper-ator V-a-p
an speculum
oper-ator n (ca. 1
oper-ator V-a-p
-ator an opercul
oper-ator V-a-p
-ator to shut,
into a lid: a
of the foot in man)
luation is retracted
luation 2: a lid
the seed plant)
oper-ata V-a-p
music opera that in
oper-ation V-a-p
-ation) + -on -ion
means a single mes
of structural g
oper-ation V-a-p
-ation (1678): t
oper-ation a

MECHANICS OF PATENT CLAIM DRAFTING

Second Edition

Eighth Printing

John L. Landis

With the Collaboration of
John D. Kaufmann, Bryan W. Sheffield
and Myron Cohen

G7-1009
Practising Law Institute
New York City

popper and is to be so claimed, and that the holes in the container (Fig. 1) are important and must be defined.

Clause (a) of Claim 1 might read:

A container for receiving kernels of corn to be popped, the container having a perforated bottom with apertures smaller in size than the kernels;

Other examples of expressions defining features of elements:

a disc of resilient material having a peripheral groove...

a relay having two windings...

a lever having a forked end and a rounded end... [If only the forked end is important to the combination being claimed, do not mention the rounded end.]

a gear of electrically insulating material...

If an element by definition inherently includes a certain feature, such feature need not be recited and it is proper to refer, without previous mention, to such features as:

the end of the lever...

the periphery of the disc...

the tines of the fork...

In case of doubt, positively describe the feature or part.

SUMMARY—Select those parts or features of each element that are essential to the combination being claimed. Then, describe them in a logical order, preferably following the main description of the element in the same clause of the claim. How many features need to be described and how broadly each should be recited is a matter of claim scope (based largely on the prior art), but the principles are the same as used in selecting the elements and naming them.

Section 23—Claiming Holes

In the situation where a hole is to be described it must not be recited positively. That is, instead of stating "a hole, groove, aper-

ture, recess, slot, etc., in the lever," one must state "... the lever having a hole, groove, etc." Thereafter, one can refer to "the hole" or "said hole." This "rule" may seem to make little sense, but it is another founded in antiquity like the single-sentence rule. Maybe someone thought that a hole is nothing—and people shouldn't claim nothing?

Another approach to describing holes is an expression such as "... the level having portions defining a hole, groove, etc." The hole is thus defined in terms of the structure which forms it.

One case *In re Newton*, 163 USPQ 34 (CCPA 1969), held that it was proper to claim a hole and its function as a means for performing a function, specifically "means for providing fluid communication between . . . [two members]."

SUMMARY—Do not claim holes positively or make them claim elements. Holes are nothing; you cannot claim nothing. Claim "a [member] having a hole," groove, slot, aperture, etc.

Section 24—Order of Elements

The elements of the claim should be presented in some logical order. Often, there are several orders that make sense, and any one may be selected. The order used in Claim 1 is a "functional" order, starting with the element which first contacts the work-piece (the container) and proceeding along functional lines to describe the remaining elements.

Another order which is often used is a "structural" order, starting first with the base, or the source of power, and proceeding along structural lines to describe the remaining elements. In structural order, Claim 1 would read:

1B. Apparatus for shaking articles, which comprises:

- (a) a base;
- (b) a plurality of parallel legs, each of which is connected pivotally at one end of the base;
- (c) a container for the articles connected pivotally to the other ends of the legs, so that the legs support the container for oscillating movement with respect to the base; and

It :
ment:
struct
low.
logica
drive:
start
of the
one p
start :
It :
cult t
mean:
SU.

Section

It i
each
coope
direct
elemen
the cl
ample
graphi
someti
such a
A real
do not
Section:
binatic
ner of
tion, e
claims